CBIC Control Number
359411

April 7, 2014

Via Federal Express

Document Processing Center (7407M)
EPA East – Room 6428
(Attn: TSCA Section 8(e) Coordinator)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

CONTAINS TSCA CONFIDENTIAL BUSINESS INFORMATION

Re: [ ]; TSCA Section 8(e) Submission for [ ] (CASRN [ ])

Dear Sir or Madam:

[ ] hereby submits to the U.S. Environmental Protection Agency (EPA) under section 8(e) of the Toxic Substances Control Act (TSCA) information regarding (1) an acute oral toxicity study in rats using a research and development (R&D) substance, [ ], with the Chemical Abstracts Service Registry Number (CASRN) [ ]; and (2) a local lymph node assay (LLNA) using the same substance.[2] This substance was imported only for internal company use under TSCA R&D exemption.

[ ] Study No. [ ] studied the acute oral toxicity of the R&D substance by single oral administration to Sprague Dawley rats, followed by a fourteen day observation period. A first subgroup of three female rats was dosed at 2000 $mg_{(dry\ salt)}$/kg-body weight. A second and third subgroup of three female rats each were dosed at 300 $mg_{(dry\ salt)}$/kg-body weight. See Attachment 1 for a summary of the results.

COMPANY SANITIZED

[2] [ ]

[ ] Study No. [ ] studied the allergenic potential of the R&D substance by local lymph node assay in three groups of five female CBA/CAOlaHsd mice at concentrations of 10%, 25%, and 50%. See Attachment 2 for a summary of the results.

If you have any questions regarding this submission, please do not hesitate to contact [ ] at [ ] or [ ].

Sincerely,

[ ]
[ ]

Enclosure: Attachment 1 - Summary of Results
Attachment 2 - Summary of Results
Attachment 3 - CBI Substantiation (CBI)

cc: [ ]

Attachment 1

Summary of Results

[ ] Study No. [ ] studied the acute oral toxicity of a research and development substance, [ ] with the Chemical Abstracts Service Registry Number (CASRN) [ ] by single oral administration to Sprague Dawley rats, followed by a fourteen day observation period. A first subgroup of three female rats was dosed at 2000 $mg_{(dry\ salt)}$/kg-bw. A second and third subgroup of three female rats each were dosed at 300 $mg_{(dry\ salt)}$/kg-bw.

All three female rats treated at 2000 $mg_{(dry\ salt)}$/kg-bw died between 2 and 4 hours after dosing. Lethargy, difficult breathing, piloerection, tremors, and salivation were observed prior to death with various incidence. At necropsy examination, dark color of the liver, brown gelatinous content, or dark areas in the stomach, and red staining on the muzzle were recorded in all animals. Red color of the thymus was recorded in two animals.

No mortality was recorded in any animals treated at 300 $mg_{(dry\ salt)}$/kg-bw. Clinical signs in the surviving animals were limited to piloerection observed at 2 and 4 hours after administration. A very slight body weight loss was detected in two animals on Day 15, without any toxicological significance; body weight changes were within the expected range for this strain and age of animals. No abnormalities were observed at necropsy examination performed at the end of the observation period in these animals.

The mortality pattern demonstrated the LD_{50} to be greater than 300 $mg_{(dry\ salt)}$/kg-bw but less than 2000 $mg_{(dry\ salt)}$/kg-bw.

Attachment 2

Summary of Results

[ ] Study No. [ ] studied the allergenic potential of a research and development substance, [ ] with the Chemical Abstracts Service Registry Number (CASRN) [ ] by local lymph node assay in CBA/CAOlaHsd mice. The LLNA was performed using the test substance in concentrations of 10%, 25%, and 50% with five female mice per group. The mice were treated by topical application at the dorsum of each ear lobe on three consecutive days.

No symptoms of local toxicity at the ears of the animals and no systemic findings were observed during the study period. Stimulation Indices of 2.32, 2.05, and 4.72 were determined with the test substance at concentrations of 10%, 25%, and 50% in propylene glycol, respectively. The study determined the test substance to be a skin sensitizer and derived an EC3 value of 33.9% (w/v) (*i.e.*, not a strong sensitizer).

ORIGIN ID:DYLA (856) 251-3404
KATHLEEN MEEHAN
SOLVAY SOLEXIS, INC.
10 LEONARD LANE

WEST DEPTFORD, NJ 08086
UNITED STATES US

SHIP DATE: 08APR14
ACTWGT: 0.3 LB
CAD: 0943884/CAFE2704

BILL SENDER

TO SECTION 8(E)
TSCA CONFINDENTIAL BUSINESS INFO
EPA EAST – ROOM 6428 US ENVIRONMENTAL
1201 CONSTITUTION AVENUE, NW
WASHINGTON DC 200043302
(202) 564 – 8940

INV:
PO:
REF:
DEPT:

FedEx
Express

WED – 09 APR AA
STANDARD OVERNIGHT

TRK# 0201 6020 0406 0191

EP RDVA

20004
DC – US IAD

Part # 156148-434 RIT2 10/11

J131113052301 26